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ATTORNEY'S DOCKET NO: C1039/7057 (HCL/MAT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis, et al.
Serial No.: 09/965,101
For: VECTORS AND METHODS FOR IMMUNIZATION OR THERAPEUTIC PROTOCOLS
Filed: September 26, 2001
Examiner: Not yet assigned
Art Unit: Not yet assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on November 12, 2001.

Maria A. Trevisan Reg. No.: 48,207

Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL

Transmitted herewith are the following documents:

- Information Disclosure Statement/1449/references cited
 Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is required. If any fee is determined to be due by the Examiner, the Examiner is authorized to charge the appropriate fee to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,

Maria A. Trevisan, Reg. No. 48,207

Wolf, Greenfield & Sacks, P.C.

Federal Reserve Plaza, 600 Atlantic Avenue
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Attorneys for Applicants

Attorney Docket No. C1039/7057
Date: November 12, 2001
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Maria A. Trevisan Reg. No.: 48,207

Commissioner for Patents
Washington, D.C. 20231

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing date of a National Application.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed):

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Title of Application</u>
C1037/7013	09/776,479	02/02/01	Immunostimulatory Nucleic Acids for the Treatment of Asthma and Allergy
C1037/7016	09/009,634	01/21/98	Immune Stimulation by Phosphorothioate Oligonucleotide Analogs
C1037/7017	09/800,266	03/05/01	Immunostimulatory Nucleic Acids and Cancer Medicament Combination Therapy for Treatment of Cancer
C1037/7018	09/801,893	03/08/01	Nucleic Acids for the Treatment of Disorders Associated with Microorganisms
C1037/7019	09/920,313	08/01/01	Nucleic Acids for Prevention and Treatment of Gastric Ulcers
C1037/7021	09/949,194	09/07/01	Nucleic Acids for the Prevention and Treatment of Sexually Transmitted Diseases
C1039/7017	09/191, 170	11/13/98	Immunostimulatory Nucleic Acid Molecules for Activating Dendritic Cells
C1039/7020	09/337,584	06/21/99	Methods for Treating Allergic and Asthmatic Disorders Using Immunostimulatory Oligonucleotides
C1039/7021	09/337,619	06/21/99	Methods for Treating Cancer Using Immunostimulatory Oligonucleotides
C1039/7022	09/337,893	06/21/99	Methods of Redirecting an Immune Response Using Immunostimulatory Oligonucleotides
C1039/7023	09/337,636	06/21/99	Immunostimulatory Nucleic Acid Molecules

C1039/7025	09/325,193	06/03/99	Use of Nucleic Acids Containing Unmethylated CpG Oligonucleotides as an Adjuvant
C1039/7027	09/306,281	05/06/99	Methods for the Prevention and Treatment of Parasitic Infections and Related Diseases Using CpG Oligonucleotide
C1039/7028	09/361,575	07/27/99	Stereoisomers of CpG Oligonucleotides and Related Methods
C1039/7029	09/415,142	10/09/99	Immunomodulatory Oligonucleotides
C1039/7035	09/669,187	09/25/00	Immunostimulatory Nucleic Acids
C1039/7036	09/559,140	04/27/00	Screening Assays for Identifying Inhibitors, Mimics, Agonists, Antagonists and Binding Compounds
C1039/7041	09/655,319	09/05/00	Immunostimulatory Oligonucleotides
C1039/7042	09/630,319	07/31/00	Methods for Treating and Preventing of Infectious Disease
C1039/7043	09/629,477	07/31/00	Methods for Treating and Preventing of Disease in Non-Human Animals
C1039/7044	09/672,126	09/27/00	Methods Related to Immunostimulatory Nucleic Acid-Induced Interferon
C1039/7048	09/818,918	03/27/01	Immunostimulatory Nucleic Acid Molecules
C1039/7049	09/824,468	04/02/01	Methods and Products for Stimulating the Immune System Using Immunotherapeutic Oligonucleotides and Cytokines

C1039/7052	09/888,326	06/22/01	Methods for Enhancing Antibody Induced Cell Lysis and Treating Cancer
C1039/7053	09/931,583	08/16/01	Methods and Products for Treating HIV Infection
C1040/7004	09/146,072	09/02/98	Nucleotide Vector, Composition Containing Such Vector and Vaccine for Immunization Against Hepatitis
C1040/7006	09/316,199	05/21/99	Methods and Products for Inducing Mucosal Immunity
C1040/7010	09/768,012	01/22/01	Immunostimulatory Nucleic Acids for Inducing a Th2 Immune Response
C1041/7002	09/241,653	02/02/99	Methods for Regulating Hematopoiesis Using Immunostimulatory CpG-Oligonucleotides
C1041/7005	09/355,254	02/22/00	Pharmaceutical Compositions Comprising a Polynucleotide and Optionally an Antigen Especially for Vaccination
C1041/7010	09/786,436	03/20/01	G-motif Oligonucleotides and Uses Thereof
C1041/7014	09/895, 007	06/28/01	Immunostimulatory Nucleic Acids for the Treatment for Anemia, Thrombocytopenia and Neutropenia

PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

PART IV: Remarks

Documents cited on the attached form PTO-1449 (modified) are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By: 

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Telephone (617) 720-3500

Docket No. C1039/7057 (HCL/MAT)

Dated: November 12, 2001

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PATENT & TRADEMARK OFFICE

FORM PTO-1449 (Modified)		ACTY. DOCKET NO.: C1039/7057	SERIAL NO.: 09/965,101
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		APPLICANT: Davis, et al.	
		FILING DATE: September 26, 2001	GROUP: Not Yet Assigned

U.S. PATENT DOCUMENTS

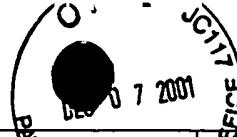
Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	*A1	3,906,092	09/16/75	Hilleman et al.	424	089	
	*A2	4,844,904	07/04/89	Hamaguchi et al.	424	450	
	*A3	4,863,740	09/05/89	Kissel et al.	424	450	
	*A4	4,975,282	12/04/90	Cullis et al.	424	450	
	*A5	5,000,959	03/19/91	Iga et al.	424	450	
	*A6	5,248,670	09/28/93	Draper et al.	514	44	
	*A7	5,580,859	12/03/96	Felgner et al.	514	44	
	*A8	5,585,479	12/17/96	Hoke et al.	536	24.5	
	*A9	5,589,466	12/31/96	Felgner et al.	514	44	
	*A10	5,663,153	09/02/97	Hutcherson et al.	514	44	
	*A11	5,679,647	10/21/97	Carson et al.	514	44	
	*A12	5,723,335	03/03/98	Hutcherson et al.	435	375	
	*A13	5,780,448	07/14/98	Davis et al.	514	44	
	*A14	5,786,189	07/28/98	Locht et al.	435	172.3	
	*A15	5,849,719	12/15/98	Carson et al.	514	44	10/04/96
	A16	6,194,388 B1	02/27/01	Krieg, et al.			
	A17	6,207,646 B1	03/27/01	Krieg, et al.			
	A18	6,239,116 B1	05/29/01	Krieg, et al.			
	A19	6,214,806 B1	04/10/01	Krieg, et al.			
	A20	6,218,371 B1	04/17/01	Krieg, et al.			

FOREIGN PATENT DOCUMENTS

	Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No
	*B1 WO 90/11092	10/04/90	PCT - Vical (Felgner)	A61K	48/00	
	*B2 WO 91/12811	09/05/91	PCT - Isis Pharmaceuticals (Draper)	A61K	31/70	
	*B3 0468520 A3	01/29/92	EPO - Mitsui Toatsu Chem. (Tokunaga)	A61K	31/70	
	*B4 WO 92/03456	03/05/92	PCT - Isis Pharmaceuticals (Anderson)	C07H	15/12	
	*B5 WO 92/18522	10/29/92	PCT - Salk Institute (Chu)	C07H	21/00	
	*B6 WO 92/21353	12/10/92	PCT - Genta (Arnold)	A61K	31/70	
	*B7 0302758 B1	03/16/94	EPO - NEMC (Androphy)	C12N	15/37	
	*B8 WO 94/19945	09/15/94	PCT - Isis Pharmaceuticals (Draper)	A01N	43/04	
	*B9 WO 95/05853	03/02/95	PCT - Regents of U. of Cal. (Carson)	A61K	48/00	
	*B10 WO 95/26204	10/05/95	PCT - Isis Pharmaceuticals (Hutcherson)	A61K	48/00	
	*B11 WO 96/02555	02/01/96	PCT - UIRF (Krieg)	C07H	21/00	
	*B12 WO 96/13277	05/09/96	PCT - Regents of U. of Cal. (Carson)	A61K	48/00	
	*B13 WO 96/14074	05/17/96	PCT - Regents of U. of Cal. (Carson)	A61K	31/70	
	*B14 WO 96/35782	11/14/96	PCT - Applied Research Systems (C12N	15/00	
	*B15 WO 97/28259	08/07/97	PCT - Regents of U. of Cal. (Carson)	C12N	15/00	

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.



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*B16	WO 98/14210	04/09/98	PCT - Regents of U. of Cal. (Carson)	A61K	39/35		
*B17	WO 98/52581	11/26/98	WIPO	A61K	35/00		
*B18	WO 99/41368A2	08/19/99	WIPO	C12N	15/10		
*B19	WO 99/41368A3	08/19/99	WIPO	C12N	15/10		
*B20	EP 0773295	05/14/97					
*B21	WO 98/18810	05/07/98	WIPO				
*B22	WO 98/37919	09/03/98	WIPO				
*B23	WO 98/40100	09/17/98	WIPO				
*B24	WO 98/52581	11/26/98	WIPO				
*B25	WO 99/51259	10/14/99	WIPO				
*B26	WO 99/56755	11/11/99	WIPO				
*B27	WO 99/58118	11/18/99	WIPO				
*B28	WO 99/61056	12/02/99	WIPO				

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(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

*C1	Adya N et al., Expansion of CREB's DNA recognition specificity by Tax results from interaction with Ala-Ala-Arg at positions 282-284 near the conserved DNA-binding domain of CREB. <i>Proc Natl Acad Sci USA</i> 91(12):5642-6, 7 Jun 1994.
*C2	Allison AC et al., The development of an adjuvant formulation that elicits cell-mediated and humoral immune responses to virus subunit and other antigens. <i>Immunopharmacology of Infections Diseases: Vaccine Adjuvants and Modulators of Non-Specific Resistance</i> , pgs. 191-201, 1987.
*C3	Angier N., Microbe DNA seen as alien by immune system, <i>New York Times</i> , 11 April 1995
*C4	Azad RF et al., Antiviral activity of a phosphorothioate oligonucleotide complementary to RNA of the human cytomegalovirus major immediate-early region. <i>Antimicrobial Agents and Chemotherapy</i> , 37:1945-1954, September, 1993.
*C5	Azuma I., Biochemical and immunological studies on cellular components of tubercle bacilli. <i>Kekkaku</i> 69(9):45-55, 1992.
*C6	Ballas ZK et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 157(5):1840-5, 1996.
*C7	Bayever, E et al., Systemic administration of a phosphorothioate oligonucleotide with a sequence complementary to p53 for acute myelogenous leukemia and myelodysplastic syndrome: initial results of a phase I trial. <i>Antisense Res Dev</i> 3:383-390, 1993.
*C8	Bennett RM et al., DNA binding to human leukocytes. Evidence for a receptor-mediated association, internalization, and degradation of DNA. <i>J Clin Invest</i> 76(6):2182-90, 1985.
*C9	Berg DJ et al., Interleukin-10 is a central regulator of the response to LPS in murine models of endotoxic shock and the Shwartzman reaction but not endotoxin tolerance. <i>J Clin Invest</i> 96(5):2339-47, 1995.
*C10	Blanchard DK et al., Interferon-gamma induction by lipopolysaccharide: dependence on interleukin 2 and macrophages. <i>J Immunol</i> 136(3):963-70, 1986.
*C11	Blaxter ML et al., Genes expressed in <i>Brugia malayi</i> infective third stage larvae. <i>Molecular and Biochemical Parasitology</i> 77:77-93, 1996.
*C12	Boggs RT et al., Characterization and modulation of immune stimulation by modified oligonucleotides. <i>Antisense Nucleic Acid Drug Dev</i> 7(5):461-71, Oct 1997.
*C13	Branda RF et al., Amplification of antibody production by phosphorothioate oligodeoxynucleotides. <i>J Lab Clin Med</i> 128(3):329-38, Sep 1996.
*C14	Branda RF et al., Immune stimulation by an antisense oligomer complementary to the rev gene of HIV-1. <i>Biochemical Pharmacology</i> 45(10):2037-2043, 1993.

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*C15	Briskin M et al., Lipopolysaccharide-unresponsive mutant pre-B-cell lines blocked in NF-kappa B activation. <i>Mol Cell Biol</i> 10(1):422-5, Jan 1990.
*C16	Burgess TL et al., The antiproliferative activity of c-myb and c-myc antisense oligonucleotides in smooth muscle cells is caused by a nonantisense mechanism. <i>Proc Natl Acad Sci USA</i> 92(9):4051-5, 1995.
*C17	Chace J et al., Regulation of differentiation in CD5+ and conventional B cells. <i>Clinical Immunology and Immunopathology</i> 68(3):327-332, 1993.
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*C20	Condon C et al., DNA-based immunization by in vivo transfection of dendritic cells. <i>Nat Med</i> 2(10):1122-8, 1996.
*C21	Corr M et al., Gene vaccination with naked plasmid DNA: mechanism of CTL priming. <i>J Exp Med</i> 184(4):1555-60, 1996.
*C22	Cowdery JS et al., Bacterial DNA induces NK cells to produce IFN-gamma in vivo and increases the toxicity of lipopolysaccharides. <i>J Immunol</i> 156(12):4570-5, 15 Jun 1996.
*C23	Crosby SD et al., The early response gene NGFI-C encodes a zinc finger transcriptional activator and is a member of the GCAGGGGGCG (GSG) element-binding protein family. <i>Mol Cell Biol</i> 2:3835-3841, 1991.
*C24	Crystal RG, Transfer of genes to humans: early lessons and obstacles to success. <i>Science</i> 270:404-410, 1995.
*C25	D'Andrea A et al., Interleukin 10 (IL-10) inhibits human lymphocyte interferon gamma-production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells. <i>J Exp Med</i> 178(3):1041-8, 1993.
*C26	Davis HL et al., CpG DNA is a potent enhancer of specific immunity in mice immunized with recombinant hepatitis B surface antigen. <i>J Immunol</i> 160(2):870-6, 1998.
*C27	Davis HL et al., Direct gene transfer into skeletal muscle in vivo: factors affecting efficiency of transfer and stability of expression. <i>Hum Gene Ther</i> 4(2):151-9, 1993.
*C28	Davis HL et al., DNA vaccine for hepatitis B: evidence for immunogenicity in chimpanzees and comparison with other vaccines. <i>Proc Natl Acad Sci USA</i> 93(14):7213-8, 1996.
*C29	Davis HL et al., DNA-based immunization induces continuous secretion of hepatitis B surface antigen and high levels of circulating antibody. <i>Hum Mol Genet</i> 2(11):1847-51, 1993.
*C30	Davis HL, Plasmid DNA expression systems for the purpose of immunization. <i>Curr Opin Biotechnol</i> 8(5):635-46, 1997.
*C31	Doe B et al., Induction of cytotoxic T lymphocytes by intramuscular immunization with plasmid DNA is facilitated by bone marrow-derived cells. <i>Proc Natl Acad Sci USA</i> 93:8578-8583, 1996.
*C32	Englisch U et al., Chemically modified oligonucleotides as probes and inhibitors, <i>Angew Chem Int Ed Engl</i> 30:613-629, 1991.
*C33	Erb KJ et al., Infection of mice with Mycobacterium bovis-Bacillus Calmette-Guerin (BCG) suppresses allergen-induced airway eosinophilia. <i>J Exp Med</i> 187(4):561-9, 16 Feb 1998.
*C34	Etchart N et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. <i>J Gen Virol</i> 78(7):1577-80, 1997.
*C35	Etlinger HM, Carrier sequence selection - one key to successful vaccines. <i>Immunology Today</i> 13(2):52-55, 1992.
*C36	Fox RI, Mechanism of action of hydroxychloroquine as an antirheumatic drug. <i>Chemical Abstracts</i> , 120:15, Abstract No. 182630 (29 April 1994).
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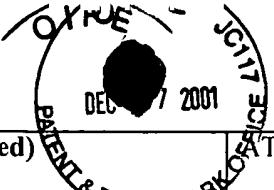
*C39	Gura, T., Antisense Has Growing Pains. <i>Science</i> 270:575-576, 1995.
*C40	Hadden JW et al., Immunopharmacology: immunomodulation and immunotherapy. <i>JAMA</i> 268(20):2964-2969, 1992.
*C41	Hadden JW, Immunostimulants. <i>TIPS</i> 14:169-174, 1993.
*C42	Halpern MD et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 167(1):72-8, 1996.
*C43	Harms JS and Splitter GA, Interferon-gamma inhibits transgene expression driven by SV40 or CMV promoters but augments expression driven by the mammalian MHC I promoter. <i>Hum Gene Ther</i> 6(10):1291-7, 1995.
*C44	Hatzfeld J et al., Release of early human hematopoietic progenitors from quiescence by antisense transforming growth factor β 1 or Rb oligonucleotides. <i>J Exp Med</i> 174:925-929, 1991.
*C45	Highfield PE, Sepsis: the more, the murkier. <i>Biootechnology</i> 12:828, 12 August 1994.
*C46	Hoeflfler JP et al., Identification of multiple nuclear factors that interact with cyclic adenosine 3',5'-monophosphate response element-binding protein and activating transcription factor-2 by protein-protein interactions. <i>Mol Endocrinol</i> 5(2):256-66, Feb 1991.
*C47	Iguchi-Ariga SM and Shaffner W, CpG methylation of the cAMP-responsive enhancer/promoter sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation. <i>Genes Dev</i> 3(5):612-9, May 1989.
*C48	International Search Report, PCT/US98/10408, WO 98/52581, 2 September 1998.
*C49	Ishikawa R et al., IFN induction and associated changes in splenic leukocyte distribution. <i>J Immunol</i> 150(9):3713-27, 1 May 1993.
*C50	Iversen P et al., Pharmacokinetics of an antisense phosphorothioate oligodeoxynucleotide against rev from human immunodeficiency virus type 1 in the adult male rat following single injections and continuous infusion. <i>Antisense Res Dev</i> 4:43-52, 1994.
*C51	Jakway JP et al., Growth regulation of the B lymphoma cell line WEHI-231 by anti-immunoglobulin, lipopolysaccharide, and other bacterial products. <i>J Immunol</i> 137(7):2225-31, 1 Oct 1986.
*C52	Jaroszewski JW and Cohen JS, Cellular uptake of antisense oligonucleotides. <i>Adv Drug Delivery Rev</i> 6(3):235-50, 1991.
*C53	Kimura Y et al., Binding of oligoguanylate to scavenger receptors is required for oligonucleotides to augment NK cell activity and induce IFN. <i>J Biochem</i> 116(5):991-994, 1994.
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*C57	Klinman DM et al., Contribution of CpG motifs to the immunogenicity of DNA vaccines. <i>J Immunol</i> 158:3635, 1997.
*C58	Klinman DM et al., CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. <i>Proc Natl Acad Sci USA</i> 93(7):2879-83, 1996.
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